



REPUBLIC OF THE PHILIPPINES
DEPARTMENT OF HEALTH
BUREAU OF FOOD AND DRUGS
Civic Drive, Filinvest Corporate City
Alabang, Muntinlupa City



21 December 2007

BUREAU CIRCULAR
No. 2007-013

SUBJECT: Updated Guidelines for the Implementation of the Association of South East Asian Nation (ASEAN) Cosmetic Directive and the Association of South East Asian Nation (ASEAN) Common Technical Documents

In order to align national standards with the ASEAN Cosmetic Directive (ACD) as declared in Administrative Order No. 2005-0015 the following guidelines are hereby adopted and all its amendments.

I. COSMETIC PRODUCT NOTIFICATION REQUIREMENTS

The company or person responsible for placing the cosmetic products in the market, shall notify BFAD where the product will be marketed of the place of the manufacture or of initial importation before the product is placed in the market.

REQUIREMENTS

1. The Documentary and Technical Requirements for Products for Notification
 - a. Completed Revised Assessment Slip (Ref. BC 20 s. 2005: Subject Revised Assessment Slips).
 - b. Completed ASEAN Notification Template.

An ASEAN Notification Template was developed to be used in all applications for cosmetic notification to facilitate compliance with the Guidelines. This form may be reproduced by applicant companies.
 - c. Valid License to Operate of the applicant
 - i. For Manufacturers – List of Product Lines must be reflected
 - ii. For Traders – List of Toll Manufacturer/s and List of Product Lines must be reflected

- iii. For Importer/Distributor – List of Product Source/s for imported cosmetic products, as well as, the Actual Manufacturer/s of the Product/s must be reflected
- iv. For Wholesaler/Distributor – List of Product Source/s must be reflected

II. PROCEDURE

A. For New Products

1. Secure the proper forms either by downloading from the BFAD Website (<http://www.bfad.gov.ph>) or by photocopying the existing prototypes.
2. Completely fill up the necessary forms. Forms should be printed in an A4 size of paper.
3. Arrange the documents accordingly in a Clear Book Filler (size A4).
4. Application for notification shall be received from Tuesday to Friday of the week until March 2008 and every Thursday and Friday of the week thereafter.
5. Two (2) copies of Notification template in original form shall be submitted. One copy to be retained by BFAD should be placed in a clear sheet and the other copy will be returned to the applicant company after appropriate acknowledgment by BFAD. Applications shall be stamped as received upon submission by the applicant of the required documents, to acknowledge receipt thereof. Notwithstanding the acknowledgement of receipt of the required documents, the BFAD reserves the right to further issue a letter/notice to the company in case of clarification or when the cosmetic product subject of the application failed to conform to any of the existing standards or specifications set by the Bureau.

B. For Existing Products

1. Submit the original acknowledged Notification Form
2. A letter informing BFAD on the specific criteria on the ASEAN Cosmetic Directive (ACD) in which the cosmetic product does not comply, if any.
3. Fill up the assessment slip identified above.
4. Application for notification of existing product shall be received from Tuesday to Friday of the week until March 2008 and every Thursday and Friday of the week thereafter.

5. Upon submission of the official receipt to Product Services Division, the original copy of acknowledged Notification Form shall be stamped for additional validity which shall be based from the date of application for the year 2007. For this purpose and consistency, those applications submitted for the year 2006 shall be treated as applied on January 2008.

The BFAD reserves the right to further issue a letter/notice to the company in case of clarification or when the cosmetic product subject of the application failed to conform, to any of the existing standards or specifications set by the Bureau.

III. NOTIFICATION LEADTIME

The notification shall be processed and completed preferably within a maximum of three (3) working days provided that the notification application complies with the requirements of this Bureau.

IV. GUIDELINES TO BE USED IN THE PROCESSING OF APPLICATIONS FOR NOTIFICATION

1. The Product Notification shall be filed only once.
2. The applicant company shall pay the appropriate amount pursuant to Administrative Order No. 50 series of 2001 (Subject: Revised Fees and Charges) and all its latest amendments; in order to render the Notification valid.
3. Types of changes for Product Notification that require letter of request and the necessary documents that affect the change(s)
 - a. Product Presentation (single product, palettes in a range, etc.)
 - b. Name and/or address of company without change of distribution rights
 - c. Authorize person representing the company
 - d. Pack sizes, packaging materials and labels

4. Types of changes that require new product notification in accordance with A.O. 2005-0025
 - a. Product name, brand name or variant name
 - b. Company change due to change of distribution rights
 - c. Product types
 - d. Intended use
 - e. Formulation
 - f. Change or addition of claims
 - g. Manufacturer/s and assembler/s (name and address)

V. NOTIFICATION VALIDITY

The notification shall be valid for a maximum of three (3) years for the new products and a staggered validity for existing products from the time of application, which will be based on the year 2007; provided, that the applicant complies with the ASEAN Cosmetic Directive (ACD) and requirements of this Bureau and that no changes has been made as specified in **Part IV** nos. **3** and **4** hereof in the approved original notification.

VI. Updates on the ASEAN Cosmetic Directive (ACD)

Appendix I ASEAN Illustrative List	September 2007
Appendix II ASEAN Labeling Requirement	December 2006
Appendix III ASEAN Claim Guideline	June 2007
ASEAN Cosmetic Directive Guidelines for Product Information File (PIF)	June 2007
ASEAN Guidelines for the Safety Assessment of a Cosmetic Product	December 2006
ASEAN Microbial Limit	June 2007
Updated Annexes of Ingredients	June to September 2007

Company/s or person/s responsible for placing the cosmetic product/s in the market are responsible for continually checking any updates and amendments to the ACD for proper guidance and compliance through the following websites:

www.bfad.gov.ph (under ASEAN Cosmetic Harmonization)

www.aseancosmetic.org

www.asean.org

VII. EFFECTIVITY

This order issued shall take effect on 03 January 2008


Prof. LETICIA BARBARA B. GUTIERREZ, M.S.
Director